K140198

MAY 1 3 2014

510(k) Summary

Product Name	IMDx HSV-1/2 for Abbott *m*2000
Sponsor	Intelligent Medical Devices, Inc. 285 Bear Hill Road Waltham, MA 02451
Correspondent	MDC Associates, LLC Fran White, Regulatory Consultant 180 Cabot Street Beverly, MA 01915

Device Identification

Trade or Proprietary Name:	IMDx HSV-1/2 for Abbott *m*2000
Common or Usual Name:	HSV-1/2 assay
Product Code:	OQO
Regulation Section:	21 CFR 866.3305
Product Classification:	Class II

Intended Use

The IMDx HSV-1/2 for Abbott *m*2000 assay is an *in vitro* diagnostic test for the direct, qualitative detection and differentiation of herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) DNA from male and female skin lesions from anogenital or oral sites. The test is intended for use as an aid in the diagnosis of HSV infection in symptomatic patients. The assay is intended to be run on the Abbott *m*2000 instrument system.

Warning: The IMDx HSV-1/2 for Abbott *m*2000 assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay is not intended for prenatal screening.

Device Description

The IMDx HSV-1/2 for Abbott *m*2000 assay uses PCR to generate amplified product from HSV-1 and HSV-2 present in clinical specimens. The presence of HSV-1 and/or HSV-2 target DNA is indicated by the fluorescent signal generated through the use of fluorescently labeled oligonucleotide probes on the Abbott *m*2000*rt* instrument. The probes do not generate a signal unless they are specifically bound to the amplified product. The amplification cycle at which fluorescent signal is detected by the Abbott *m*2000*rt* is inversely proportional to the HSV-1 and/or HSV-2 DNA target concentration present in the original specimen. A plasmid construct containing DNA unrelated to HSV-1 and HSV-2 is introduced into each specimen during sample preparation to serve as an internal control. The internal control is amplified in the same reaction as the HSV-1 and HSV-2 DNA targets, and serves to demonstrate that the sample preparation and amplification processes have proceeded correctly for each specimen. A preparation of intact, inactivated HSV-1 and HSV-2 virus is included as the positive control in the IMDx HSV-1/2 for Abbott *m*2000 assay. Run as a separate control, the positive control serves to demonstrate that the HSV-1/2 PCR reagents are functional. In addition, the positive control functions as

a process control to demonstrate that sample preparation has proceeded correctly during the run. A negative control consisting of M4RT viral transport medium is included in each run to independently verify the absence of contaminating target material in assay reagents.

Substantial Equivalency

The IMDx HSV-1/2 for Abbott *m*2000 is substantially equivalent to the Eragen Bioscience, Inc MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit. (K100336). Table 1 compares the characteristics of the IMDx HSV-1/2 for Abbott *m*2000 assay (New Device) and the MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit (Predicate Device). The differences noted do not impact the intended use and do not raise questions as to the safety and effectiveness of the test (new) device.

Table 1. Substantial Equivalence

Similarities		
Characteristic	**Eragen Biosciences MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit**	**IMDx HSV-1/2 for Abbott *m*2000 Assay (New Device)**
510(k)	K100336	TBD
Regulation	21 CFR 866.3305	21 CFR 866.3305
Product Code	OQO	OQO
Device Class	Class II	Class II
Intended use	The MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit is a polymerase chain reaction (PCR)-based qualitative *in vitro* diagnostic test for the detection and typing of herpes simplex virus (HSV1&2) DNA in vaginal lesions. It is indicated for use in the detection and typing of HSV-1 or HSV-2 in vaginal lesion swab specimens from symptomatic female patients as an aid in the diagnosis of genital herpes infection. ***Warning:*** The device is not FDA cleared for the use with cerebral spinal fluid (CSF) or any lesions other than vaginal. The assay is not intended to be used for male penile specimens, for prenatal screening, or females under the age of 18 years.	The IMDx HSV-1/2 for Abbott *m*2000 assay is an *in vitro* diagnostic test for the direct, qualitative detection and differentiation of Herpes Simplex Virus type 1 (HSV-1) and type 2 (HSV-2) DNA from male and female skin lesions from anogenital or oral sites. The test is intended for use as an aid in the diagnosis of HSV infection in symptomatic patients. The assay is intended to be run on the Abbott *m*2000 instrument system. ***Warning:*** The IMDx HSV-1/2 for Abbott *m*2000 assay is not FDA-cleared for use with cerebrospinal fluid (CSF). The assay is not intended for pre-natal screening.
Test Principle	Real-time PCR DNA amplification	Real-time PCR DNA amplification
Assay Results	Qualitative detection and differentiation of HSV-1 and HSV-2	Qualitative detection and differentiation of HSV-1 and HSV-2

Differences		
Characteristic	**Eragen Biosciences MultiCode®-RTx Herpes Simplex Virus 1 & 2 Kit**	**IMDx HSV-1/2 for Abbott *m*2000 Assay (New Device)**
Instrumentation	Sample extraction using Roche MagNA Pure System or bioMérieux NucliSENS system. Real-time PCR amplification/ detection using the Roche LightCycler 1.2 instrument.	Sample extraction and real-time PCR amplification/detection using the Abbott *m*2000 system.
Detection Method	Pairs fluorescent-labeled primers with quencher labeled nucleotides. Measures decrease in assay fluorescence with each PCR cycle.	Double-labeled (fluorophore and quencher) hydrolysis probes. Measures increase in assay fluorescence with each PCR cycle.
Sample type	Female vaginal lesions	Male and female skin lesions from anogenital or oral sites

Performance Characteristics

Clinical Performance Characteristics

Prospective Studies: The performance of the IMDx HSV-1/2 for Abbott *m*2000 assay was evaluated at four geographically diverse locations within the United States from 2012 to 2013. A total of 954 prospective specimens (807 anogenital and 147 oral) were included in the final data set and analyzed for product performance as compared to results obtained from the ELVIS® (Enzyme Linked Virus Inducible System) HSV ID and D^3 Typing Test System (Diagnostic Hybrids, Athens, OH).

One hundred and sixty one (161) anogenital prospective specimens identified as HSV-2 positive by ELVIS viral culture were removed from the initial 807 anogenital specimens for the calculation of the HSV-1 clinical performance. Two oral specimens identified as HSV-2 positive by ELVIS viral culture were removed from the initial 147 oral specimens for the calculation of the HSV-1 clinical performance.

Table 2. Summary of HSV-1 Results for Anogenital Specimens (Prospective Study)

HSV-1		Reference Method		
		POS	**NEG**	**Total**
IMDx	**POS**	101	20[a]	121
	NEG	1[b]	524	525
	Total	102	544	646
Sensitivity; 95% CI		99.0% (101/102) 95% CI [94.7% - 99.8%]		
Specificity; 95% CI		96.3% (524/544) 95% CI [94.4% - 97.6%]		

[a] Discordant analysis was performed for 17 of the 20 specimens identified as HSV-1 positive by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-1 was detected in 6 of the 17 specimens. The remaining 11 specimens remained discordant (HSV-1 was not detected).

[b] Discordant analysis was performed for the single specimen identified as HSV-1 negative by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-1 was not detected in this specimen and HSV-2 was detected in this specimen.

Table 3. Summary of HSV-2 Results for Anogenital Specimens (Prospective Study)

HSV-2		ELVIS HSV ID and D³ Typing		
		POS	NEG	Total
IMDx	POS	157	68[a]	225
	NEG	4[b]	578	582
	Total	161	646	807
Sensitivity; 95% CI		97.5% (157/161) 95% CI [93.8% - 99.0%]		
Specificity; 95% CI		89.5% (578/646) 95% CI [86.9% - 91.6%]		

[a] Discordant analysis was performed for 62 of the 68 specimens identified as HSV-2 positive by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-2 was detected in 55 of the 62 specimens. The remaining 7 specimens remained discordant (HSV-2 was not detected).

[b] Discordant analysis was performed for 2 of the 4 specimens identified as HSV-2 negative by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-2 was not detected in either specimen.

Table 4. Summary of HSV-1 Results for Oral Specimens (Prospective Study)

HSV-1		Reference Method		
		POS	NEG	Total
IMDx	POS	37	24[a]	61
	NEG	0	84	84
	Total	37	108	145
Sensitivity; 95% CI		100.0% (37/37) 95% CI [90.6% - 100.0%]		
Specificity; 95% CI		77.8% (84/108) 95% CI [69.1% - 84.6%]		

[a] Discordant analysis was performed for the 24 specimens identified as HSV-1 positive by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-1 was detected in 14 of the 24 specimens. The remaining 10 specimens remained discordant (HSV-1 was not detected).

Table 5. Summary of HSV-2 Results for Oral Specimens (Prospective Study)

HSV-2		Reference Method		
		POS	NEG	Total
IMDx	POS	0	2[a]	2
	NEG	2[b]	143	145
	Total	2	145	147
Sensitivity; 95% CI		0.0% (0/2) 95% CI [0.0% - 65.8%]		
Specificity; 95% CI		98.6% (143/145) 95% CI [95.1% - 99.6%]		

[a] Discordant analysis was performed for the 2 specimens identified as HSV-2 positive by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-2 was detected in both specimens.

[b] Discordant analysis was performed for the 2 specimens identified as HSV-2 negative by the IMDx HSV-1/2 for Abbott *m*2000 assay. HSV-2 was not detected in either specimen. HSV-1 was detected in both specimens.

Retrospective Studies: A total of 54 retrospective specimens (27 anogenital and 27 oral) were tested with the IMDx HSV-1/2 for Abbott *m*2000 assay and results were compared to historical results for the ELVIS® HSV ID and D³ Typing Test System. Twelve (12) anogenital specimens identified as HSV-2 positive by ELVIS viral culture were removed from the initial 27 anogenital specimens for the calculation of the HSV-1 clinical performance. There was no HSV-2 positive detected in 27 oral specimens.

Table 6. Summary of HSV-1 Results for Anogenital Specimens (Retrospective Study)

HSV-1		Reference Method		
		POS	NEG	Total
IMDx	POS	14	0	14
	NEG	1	0	1
	Total	15	0	15
Sensitivity; 95% CI		93.3% (14/15) 95% CI [70.2% - 98.8%]		
Specificity; 95% CI		N/A		

Table 7. Summary of HSV-2 Results for Anogenital Specimens (Retrospective Study)

HSV-2		Reference Method		
		POS	NEG	Total
IMDx	POS	12	1	13
	NEG	0	14	14
	Total	12	15	27
Sensitivity; 95% CI		100.0% (12/12) 95% CI [75.7 – 100.0%]		
Specificity; 95% CI		93.3% (14/15) 95% CI [70.2% - 98.8%]		

Table 8. Summary of HSV-1 Results for Oral Specimens (Retrospective Study)

HSV-1		Reference Method		
		POS	NEG	Total
IMDx	POS	27	0	27
	NEG	0	0	0
	Total	27	0	27
Sensitivity; 95% CI		100.0% (27/27) 95% CI [87.5% - 100.0%]		
Specificity; 95% CI		N/A		

Table 9. Summary of HSV-2 Results for Oral Specimens (Retrospective Study)

HSV-2		Reference Method		
		POS	NEG	Total
IMDx	POS	0	0	0
	NEG	0	27	0
	Total	0	27	27
Sensitivity; 95% CI		N/A		
Specificity; 95% CI		100.0% (27/27) 95% CI [87.5% - 100.0%]		

HSV-2 Oral Contrived Specimen Study: A contrived specimen study was performed to provide additional performance data for detection of HSV-2 in oral samples. HSV-negative oral samples (culture negative and PCR negative) used for the contrived study were remainders from the clinical specimens used for the method comparison study. Thirty (30) contrived HSV-2 positive oral samples were prepared by spiking HSV-2 virus into HSV-negative oral samples. HSV-2 virus was spiked in

HSV-negative oral samples at concentrations 2-3X LoD, 10X LoD, 100X LoD, 1,000X LoD and 10,000X LoD. In addition, fifteen (15) HSV-1 true positive oral and fifteen (15) HSV-negative oral samples remaining from the clinical specimens used for the method comparison study were also tested. All samples were randomized and blinded to the operator prior to testing. HSV-2 was detected in all contrived samples at all concentrations tested.

Analytical Performance Characteristics

Precision/Reproducibility:

A seven-member panel was used for all studies. Panel members were formulated with a single target present (HSV-1 MacIntyre strain or HSV-2 MS strain) at three concentrations: ~2-3X LoD (Positive), 1X LoD (Low Positive), and <1X LoD (High Negative). A true negative sample, where no HSV had been added, was also prepared using M4RT viral transport media.

Within Laboratory Repeatability

The seven-member panel was tested twice a day for a total of twelve days. Panel members were tested in replicates of three for each run (for a total of 504 data points for the 24 runs). The entire study was conducted by one trained technician using one instrument pair (Abbott *m*2000*sp* and Abbott *m*2000*rt*) and one reagent lot of the IMDx HSV-1/2 for Abbott *m*2000 assay.

Table 10. Within-Laboratory Repeatability

Panel Member	Level	Agreement with expected results	95% Confidence Interval	Avg. CN	SD CN	%CV CN
HSV-1 Positive	2-3X LoD	100.00% (72/72)	100.00% - 100.00%	36.86	0.44	1.19%
HSV-1 Low Positive	~1X LoD	100.00% (72/72)	100.00% - 100.00%	38.35	0.62	1.62%
HSV-1 High Negative	<1X LoD	44.44% (32/72)	34.02% - 54.87%	40.00	0.91	2.27%
HSV-2 Positive	2-3X LoD	100.00% (72/72)	100.00% - 100.00%	37.58	0.62	1.66%
HSV-2 Low Positive	~1X LoD	100.00% (72/72)	100.00% - 100.00%	39.16	0.59	1.52%
HSV-2 High Negative	<1X LoD	34.72% (25/72)	20.12% - 49.32%	41.48	1.42	3.42%
Negative	N/A	100.00% (72/72)	100.00% - 100.00%	N/A	N/A	N/A

Reproducibility

The same panel described above was used in the reproducibility studies. Each panel member was tested in replicates of three, for five days, at three study sites. Testing at each site was performed by two operators; each operator ran the panel once a day. The entire study was conducted using one instrument system (Abbott *m*2000*sp* and Abbott *m*2000*rt*) at each site and one reagent lot of the IMDx HSV-1/2 for Abbott *m*2000 assay.

Table 11. Reproducibility

		Site 1		Site 2		Site 3		All 3 Sites	
Panel Member	**Level**	**Agreement with expected result**	**Avg. CN (%CV)**	**Agreement with expected result**	**Avg. CN (%CV)**	**Agreement with expected result**	**Avg. CN (%CV)**	**% Agreement (95% CI)**	**Avg. CN (%CV)**
HSV-1 Positive	**2-3X LoD**	100% (30/30)	37.01 (1.3%)	100% (30/30)	37.12 (1.1%)	100% (30/30)	36.67 (1.1%)	100% (100 - 100%)	36.93 (1.3%)
HSV-1 Low Positive	**~1X LoD**	100% (30/30)	38.50 (1.6%)	96.67% (29/30)	38.63 (2.5%)	100% (30/30)	38.13 (1.5%)	98.89% (94.11 - 100%)	38.42 (1.9%)
HSV-1 High Negative	**<1X LoD**	53.33% (16/30)	39.79 (1.5%)	50.00% (15/30)	39.91 (2.0%)	36.67% (11/30)	39.75 (2.2%)	46.67% (24.77 - 68.57%)	39.81 (1.9%)
HSV-2 Positive	**2-3X LoD**	100% (30/30)	37.70 (1.5%)	100% (30/30)	37.87 (1.0%)	100% (30/30)	37.61 (1.1%)	100% (100 - 100%)	37.73 (1.2%)
HSV-2 Low Positive	**~1X LoD**	100% (30/30)	39.26 (1.9%)	100% (30/30)	39.52 (2.0%)	100% (30/30)	39.05 (1.5%)	100% (100 - 100%)	39.28 (1.9%)
HSV-2 High Negative	**< 1X LoD**	53.33% (16/30)	41.45 (2.0%)	50.00% (15/30)	41.95 (2.5%)	63.33% (19/30)	41.69 (3.3%)	55.56% (38.32 - 72.79%)	41.70 (2.6%)
HSV Negative	**N/A**	100% (30/30)	N/A	100% (30/30)	N/A	100% (30/30)	N/A	100% (100 - 100%)	N/A

Cross Reactivity & Microbial Interference:

A panel consisting of 50 organisms and human DNA (see Table 12) was tested for cross-reactivity and interference with the IMDx HSV-1/2 for Abbott *m*2000 assay. Bacteria were tested at a concentration of $\geq 1 \times 10^6$ CFU/mL and viruses were tested at a concentration of $\geq 1 \times 10^5$ $TCID_{50}$/mL. For bacteria that were difficult to obtain or grow, purified DNA was used in the place of the intact microorganism, and tested at a concentration of $\geq 1 \times 10^6$ genome copies/mL. Human DNA was tested at a concentration of 1×10^5 genome copies/mL. Strains were prepared at IMDx or obtained from Zeptometrix Corporation. All samples were prepared by diluting microorganisms or DNA into M4RT viral transport medium. No evidence of cross-reactivity or microbial interference was observed for any of the 50 test microorganisms included in the analysis. Similarly, no evidence of cross-reactivity or microbial interference was observed for human DNA.

Table 12. Cross Reactivity and Microbial Interference Panel.

Organism	**Organism**
Acinetobacter calcoaceticus var. anitratus [IHC]	*Lactobacillus acidophilus* [QC]
Acinetobacter lwoffii [QC]	*Mobiluncus curtisii*, V125 [DSM 2711] [QC]
Adenovirus 2 [QC]	*Mobiluncus mulieris*, BV 64-5 [QC]
Bacteroides fragilis [QC]	*Moraxella catarrhalis* [QC]
Candida albicans [QC]	*Mycoplasma hominis*, PG21 [GD]

Organism	Organism
Candida glabrata [QC]	*Neisseria gonorrhoeae* [GD]
Candida guilliermondii [QC]	*Neisseria meningitidis* [QC]
Candida krusei [QC]	*Prevotella melaninogenica* [QC]
Candida lusitaniae [IHC]	Rubella virus [QC]
Candida parapsilosis [QC]	Simian Virus type 40 (SV40) PML-1 (EK) [GD]
Candida tropicalis [QC]	*Staphylococcus agalactiae*, Serotype III [IHC]
Chlamydia trachomatis, LGV-II434 [QC/GD]	*Staphylococcus agalactiae*, Serotype V [IHC]
Chlamydia trachomatis, UW-3/Cx [GD]	*Staphylococcus aureus* (MRSA) [IHC]
Cytomegalovirus, AD-169 [QC]	*Staphylococcus aureus* [IHC]
Enterobacter cloacae [QC]	*Staphylococcus epidermidis* [IHC]
Enterovirus Type 71 [QC]	*Staphylococcus saprophyticus* [IHC]
Epstein-Barr Virus [QC]	*Streptococcus mitis* [QC]
Escherichia coli [QC]	*Streptococcus mutans* [QC]
Fusobacterium nucleatum, VPI 4355 [IHC]	*Streptococcus pneumoniae* [QC/GD]
Gardnerella vaginalis [QC]	*Streptococcus pyogenes* [QC]
Haemophilus ducreyi, Class I [GD]	*Streptococcus salivarius* [IHC]
Human Herpesvirus 6 (HHV-6) [QC]	*Toxoplasma gondii* [QC]
Human Herpesvirus 7 (HHV-7) [QC]	*Trichomonas vaginalis* Donne [GD]
Human papillomavirus 16 (HPV-16) [GD]	Varicella-Zoster Virus (HHV-3) Ellen [GD]
Human papillomavirus 18 (HPV-18) [GD]	Human DNA [GD]
Klebsiella pneumonia [QC]	

GD: Purified genomic DNA; QC: quantitated cultures from external source; IHC: culture prepared and quantitated by IMDx

Interfering Substances:

The IMDx HSV-1/2 for Abbott *m*2000 assay was challenged with twenty-eight substances that may be present at sampling sites. The substances included: anti-fungal/anti-itch vaginal cream, feminine care products, condoms with spermicidal lubricant, oral cold sore treatments, oral care products, anti-hemorrhoid cream, blood and urine. No assay interference was observed for any of the substances.

Analytical Sensitivity (Limit of Detection):

The LoD is defined as the HSV-1/2 titer (CFU/mL) detected with a probability of 95% or greater. The LoD of the IMDx HSV-1/2 for Abbott *m*2000 assay was determined for two strains of HSV-1 and two strains of HSV-2 using probit analysis. The results, representative of the analytical sensitivity of the IMDx HSV-1/2 for Abbott *m*2000 assay, are summarized in Table 13.

Table 13. Limit of Detection.

Strain	Limit of Detection (95% CI)
HSV-1 MacIntyre	13.5 $TCID_{50}$/mL (10.5 – 20.1)
HSV-1 Isolate 1	7.6 $TCID_{50}$/mL (5. 9 – 10.9)
HSV-2 MS	0.7 $TCID_{50}$/mL (0.5 – 1.0)
HSV-2 Isolate 1	219.4 $TCID_{50}$/mL (178. 5 – 305.4)

Analytical Reactivity:
Forty clinical isolates (20 HSV-1 and 20 HSV-2) were tested for reactivity with the IMDx HSV-1/2 for Abbott *m*2000 assay. Strains were tested in triplicate at 3X LoD. All strains were detected by the assay, demonstrating that the IMDx HSV-1/2 for Abbott *m*2000 assay can detect a broad range of both HSV-1 and HSV-2 isolates.

Conclusions
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

INTELLIGENT MEDICAL DEVICES, INC.
C/O FRAN WHITE, REGULATORY CONSULTANT
MDC ASSOCIATES, LLC
180 CABOT STREET
BEVERLY, MA 01915

May 13, 2014

Re: K140198
Trade/Device Name: IMDx HSV-1/2 for Abbott *m*2000
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes Simplex Virus Nucleic Acid Amplification Assay
Regulatory Class: II
Product Code: OQO
Dated: April 15, 2014
Received: April 17, 2014

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Sally A. Hojvat, M. Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K140198

Device Name: IMDx HSV-1/2 for Abbott m2000 assay

Indications for Use:

The IMDx HSV-1/2 for Abbott *m*2000 assay is an *in vitro* diagnostic test for the direct, qualitative detection and differentiation of herpes simplex virus type 1 (HSV-1) and type 2 (HSV-2) DNA from male and female skin lesions from anogenital or oral sites. The test is intended for use as an aid in the diagnosis of HSV infection in symptomatic patients. The assay is intended to be run on the Abbott *m*2000 instrument system.

Warning: The IMDx HSV 1/2 for Abbott *m*2000 assay is not FDA cleared for use with cerebrospinal fluid (CSF). The assay is not intended for prenatal screening.

Prescription Use		Over-The-Counter Use
X	AND/OR	
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Stephen J. Lovell -S
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